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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,103	06/05/2006	Alexander V. Bocharov	6137NIDDK-2-PUS	5365

88195 7590 07/21/2010

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
07/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,103	BOCHAROV ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *2, 4, 14-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group II invention (claim 3 along with linking claims 1 and 5-13) and election of SEQ ID NO: 10 as a species of the molecule and inflammation as the disease condition in the reply filed on 7/6/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. The instant specification contains numerous citations to patent and non-patent literature throughout the document. The citations have not been submitted in the form of IDS along with legible copies of the same to the office for consideration.

Specification

The lengthy specification (114 pages) has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation

is requested in correcting any errors of which applicant may become aware in the specification.

Status of pending claims

Claims 1-26 are pending.

Claims 2 and 4 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/6/10.

Claims 14-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/6/10.

Claims 1, 3 and 5-13 are examined on the merit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,156,727 issued to Garber in light of Selzman *Ann Thorac Surg* 2001;71:2066-2074.

In the instant invention, applicants claim a method for treatment of inflammation comprising providing to a recipient a physiologically effective amount of a pharmaceutical composition of a molecule that targets SR-B1/CLA-1.

Applicants elect, Asp Trp Leu Lys Ala Phe Tyr Asp Lys Val Ala Glu Lys Leu Lys Glu Ala Phe Pro Asp Trp Leu Lys Ala Phe Tyr Asp Lys Val Ala Glu Lys Leu Lys Glu Ala Phe (SEQ ID NO: 10), a peptide as the molecule that is present in the pharmaceutical composition of the instant method. The peptide SEQ ID NO: 10 disclosed by Garber is also known as 18A-Pro-18A, wherein an amphipathic peptide 18A synthesized as a head-to-tail dimer with a proline incorporated (column 6, lines 38-40).

Garber discloses the peptide of instant invention SEQ ID NO: 1 (column 6, column 17 and elsewhere in the document) and discloses that the pharmaceutical composition of the peptide (column 15, lines 1-3) and the composition is administered to fat sensitive mice the atherosclerosis lesions (Example 11, column 13). Atherosclerosis lesion is caused by inflammation as illustrated by Selzman (Figure 3 and page 2072, column 2). This reads on the instant claims 1, 3, 5, 8 and 11. The amphipathic peptide 18A-Pro-18A competes with HDL for binding and HDL has been shown to deliver cholesterol to the cells through class B scavenger receptor SRB1. This reads on the instant claims 7 and 10. Garber also discloses that a dosage of peptide to be injected was selected based on the in vivo studies conducted using 18A peptide to inhibit the LPS-induced toxicity in mice (Example 3, lines 27-30). This reads on the instant claim 7. Garber discloses the administration of SEQ ID NO: 10 of the instant invention to fat sensitive mice and hence it inherently exhibits the Kd lower than 10^{-7} to SR-B1 receptor. Hence, Garber anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim1, 3 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,156,727 issued to Garber in view of US 6,664,230 issued to Fogelman in light of Selzman, *Ann Thorac Surg,* 2001;71:2066-2074.

In the instant invention, applicants claim a method for treatment of inflammation comprising providing to a recipient a physiologically effective amount of a pharmaceutical composition of a molecule that targets SR-B1/CLA-1.

Applicants elect, Asp Trp Leu Lys Ala Phe Tyr Asp Lys Val Ala Glu Lys Leu Lys Glu Ala Phe Pro Asp Trp Leu Lys Ala Phe Tyr Asp Lys Val Ala Glu Lys Leu Lys Glu Ala Phe (SEQ ID NO: 10), a peptide as the molecule that is present in the pharmaceutical composition of the instant method. The peptide SEQ ID NO: 10 disclosed

by Garber is also known as 18A-Pro-18A, wherein an amphipathic peptide 18A synthesized as a head-to-tail dimer with a proline incorporated (column 6, lines 38-40).

Garber discloses the peptide of the instant invention SEQ ID NO: 1 (column 6, column 17 and elsewhere in the document) and discloses that the pharmaceutical composition of the peptide (column 15, lines 1-3) and the composition is administered to fat sensitive mice the atherosclerosis lesions (Example 11, column 13). Atherosclerosis lesion is caused by inflammation as illustrated by Selzman (Figure 3 and page 2072, column 2). This reads on the instant claims 1, 3, 5, 8 and 11. The amphipathic peptide 18A-Pro-18A competes with HDL for binding and HDL has been shown to deliver cholesterol to the cells through class B scavenger receptor SRB1. This reads on the instant claims 7 and 10. Garber also discloses that a dosage of peptide to be injected was selected based on the in vivo studies conducted using 18A peptide to inhibit the LPS-induced toxicity in mice (Example 3, lines 27-30). This reads on the instant claim 7. Garber discloses the administration of SEQ ID NO: 10 of the instant invention to fat sensitive mice and hence it inherently exhibits the Kd lower than 10^{-7} to SR-B1 receptor.

Garber does not disclose peptides composed of D-amino acid residues.

Fogelman discloses peptide that comprises of essentially every enantiomeric amino acid is a D-amino acid (column 17, line 55 to column 18, line 8). This reads on the instant claims 9 and 12. The peptide SEQ ID NO: 1, disclosed by Fogelman is 18A peptide of Garber. Fogelman also discloses that peptides synthesized with D-amino acid residues are more resistant to digestion in stomach (*in vivo* studies) and hence was able to perform better than the peptides synthesized with L-amino acids. However, the performance of both L- and D-peptides were comparable in *in vitro* studies. This is

indicative of the fact that peptides comprising of D-amino acids were resistant to degradation in stomach.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Garber and Fogelman to arrive at the instant invention as Garber discloses the method of treating inflammation with the elected peptide of the instant peptide and Fogelman teaches the peptides wherein L- isomers were replaced with D-isomers of amino acids residues. One would have been motivated to combine the teachings of Garber and Fogelman in light of information available form Selzman given the fact that peptides synthesized with D-amino acids are resistant to degradation in stomach and are as effective as peptides made of L-amino acids. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SATYANARAYANA R. GUDIBANDE/
Examiner, Art Unit 1654

/Andrew D Kosar/
Primary Examiner, Art Unit 1654